A STUDY ON CORRELATION OF MICROBIAL CULTURE OF STENT AND SYMPTOMATOLOGY IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS (LUTS) AFTER DJ STENTING

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CERTIFICATE

This is to certify that this dissertation entitled **"A STUDY ON CORRELATION OF MICROBIAL CULTURE OF STENT AND SYMPTOMATOLOGY IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS (LUTS) AFTER DJ STENTING"** submitted by **Dr. T.SRINIVASAN** appearing for **M.Ch (Urology)** degree examination in August 2014 is a original bonafide record of work done by him during the academic period of August 2011 to July 2014 under direct supervision and guidance in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R. Medical University, Chennai, Tamilnadu, India.

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TABLE OF CONTENTS

ABSTRACT

CORRELATION OF MICROBIAL CULTURE OF STENT AND SYMPTOMATOLOGY IN PATIENTS WITH LOWER URINARY TRRACT SYMPTOMS (LUTS) AFTER DJ STENTING

AIM :

To compare the microbial culture of DJ stents to that of symptomatology, in patients having lower urinary tract symptoms after DJ stenting.

MATERIALS AND METHODS:

Patients who were admitted in Kilpauk Medical College and Govt. Royapettah Hospital and undergone DJ stenting following which they developed significant lower urinary tract symptoms were included in the study. 45 patients were followed up prospectively and were observed and assessed for severity of stent related lower urinary tract symptoms using IPSS questionnaire.Vesical end of DJ stent was subjected to microbial culture and sensitivity. The result of microbial culture positivity of DJ stent was correlated to IPSS score, status of urine microbial culture, the relevance to timing of stent removal and other parameters

RESULTS:

The mean age of the study group was30.71 years. 28 were males and 17 were females.16 patients had stent on the right side and 25 had on the left side. 4 patients had bilateral stenting. The mean IPSS score was 20.25. Dysuria was predominant in 66.4%, frequency in 22.7% and urgency in 7.2 %. Female patients had more incidences of severe IPSS. Moderate IPSS (8-19) noted predominantly in 26-30 years.in the group 31-35 years it was predominantly severe (IPSS 20-35).62.2% gave Quality of Life score of 4. 15.5% had a score of 5. 8 patients gave the score as 3 and 2 patients gave a score 6. Adjusted to bilaterality, DJ stent culture was most commonly E.coli followed by kelbsiella,pseudomonas,enterococcus. The same pattern of hierarchy noted in urine culture. When analysed with SPSS v2 software, age and sex were not significant determinant of positive stent culture, nor they predicted severe IPSS

score. IPSS score correlated positively with DJ stent culture. Statistical significance was seen when IPSS was tested against combine positivity of DJ and urine culture (P value 0.001). Urine culture in predicting positive stent culture had 48.3% accuracy. Stent removal was early in patients with severe IPSS and was statistically significant when correlated to combined microbial positive culture (P value 0.003)

CONCLUSION:

Stent related symptoms are a significant problem and the prevalence is common. Age and sex of the patient does not predict severity of stent related symptoms nor they are linked to positive stent culture. The quality of life based on IPSS questionnaire shows that majority of the patients are unhappy with the bothersome nature of stent related symptoms. Early stent removal was statistically associated with positive microbial culture (DJ stent, urine and combined) and severity of IPSS. Urine culture is not a strongly predictive variable for positive DJ stent culture.

INTRODUCTION

By definition, the double-J or pigtail stent is a tube placed within the ureteral lumen in a retrograde or antegrade fashion in order to maintain its patency. The double-J ureteral stent had been widely applied during the endourologic surgery to relieve or prevent ureteral obstruction. Stent-related morbidities, such as lower urinary tract symptoms (LUTS), stent-related body pain and hematuria, are bothersome and might have a negative impact on quality of life (QoL) and sexual performance for both genders. Stent discomfort can vary from one patient to another in an idiosyncratic manner, but is believed to affect over 80% of patients. The prevalence hence is significant and geographic[4]variance might exist. This makes this issue an important health problem and indirectly serves as a scale for quality of healthcare delivery to the public. The pathophysiology of stent-related symptoms remains unclear. However, the pain and LUTS caused by stent placement has been attributed lower ureter and bladder spasm due to local irritation of the stent. Studies utilizing pharmaco therapeutic agents like Tamsulosin and other antimuscarinics and α–blockers were shown to improve symptoms but the benefit is obtained by preventing unwarranted bladder[5]contractility or other unknown mechanism (in case of α–blockers) . In all these studies the primary problem is not addressed and remains unknown. Patients who fail to respond to

such pharmacotherapy are left with limited options or else removal of the stent (irrespective of the consequence). Also, attempt to modify the design of bladder end of the stent was studied (James E. Lingeman et. al). The results showed no significant difference among the groups. A complete understanding of the pathogenesis of stent-related symptoms is limited by the lack of systematic analysis of the same. The role of micro-organisms (pathogenic/opportunistic) in this scenario is less investigated and reported.

An important problem here is to develop a validated[22,] reliable and simple tool for symptom analysis. Ureteral Stent Symptoms Questionnaire (USSQ) is a very useful standard tool for such analysis. USSQconsists of 38 items and 6 subdivisions: overall general health,pain, work performance, voiding symptoms, sexual matters, and additional problems. USSQ is a lengthy and complicated instrument. Its very complexity poses problem when it is applied to large population. Furthermore it has been shown that such complex questionnaire requires certain minimum comprehensive capacity on the patient part which is of definite concern in reference to our society, as well as in other developing nations. IPSS scores over USSQ in its relative simplicity. The real need is development and validation of an ideal research tool that should first address the needs of our society, which is ironically lacking till date[18].

This study in part tries to address some of the questions raised above.

AIM OF THE STUDY

To compare the microbial culture of DJ stents to that of symptomatology, in patients having lower urinary tract symptoms after DJ stenting.

REVIEW OF LITERATURE

HISTORY OF EVOLUTION OF URETERAL STENT:

Ureteral stents are used to ensure patency of ureter in situations where it could be compromised. Their primary purpose is to ensure urine drainage from renal pelvis to urinary bladder. Mostly they are used for temporary relief of obstruction of ureter. In 1800 A.D Dr. Gustav Simon describes inserting a tube into a ureter during open bladder surgery. He is credited with being the first person to "stent" a ureter. In 1900A.D Dr. Joaquin Albarranocreated the first ureteral stent. Stents at that time were typically made of fabric covered in lacquer varnish. In 1967 Dr. Paul Zimskind reports insertion a straight silicone tube into a ureter to relieve obstruction. In their report, they referred to the device as a "ureteral splint". This is the first use of a stent that is placed endoscopically (using a camera) instead of through an open incision. It represents the beginning of the modern era of ureteral stents. However, because the stent is straight, these stents are prone to accidentally slip out. Dr. James Montie coined the term "stent" to refer to indwelling tubes placed in the urinary tract in the year 1973. The common problem with the early stents was their tendency to migrate.In the year 1974 McCullough described the use of a "shepherds crook" stent to prevent the stent from slipping down and out of the kidney. The shepherds crook design was borrowed from

existing stents meant for insertion into blood vessels. While the stent no longer migrated downwards due to the upper curl, it was still prone to slipping upwards into the kidney. The important problem of stent migration was solved in 1978 when double-J (DJ) stents were described by Finney. The tips of these stents are J-shaped on either side to prevent upward or downward migration; hence they got their name “Double J”. Further advancements[14] made in 1989, when amagnetic tipped “Magnetip” double J ureteral stent is introduced by ACMI. This can be removed using a magnet instead of by cystoscopy (insertion of a camera). However, it is no longer on the market, probably because removal using a “Magnetriever” was not always reliable. In one study, only 86% of Magnetip stents were removed successfully, while the others required traditional cystoscopy for removal. Despite enormousadvancement in stent biomaterials and design, DJ stents are not free of complications and problems and the search for an ideal DJ stent may remain utopian. DJ stents are usually made from silicon or polyurethane. They are available in different sizes and length. Commonly used stents are of 24-30 cm length. They are inserted commonly with help of cystoscopy or ureteroscopy during an endourological procedure. Removal of the stents may be simple pulling of threads(in case of stents with threads attached) or may require cystoscopy for removal. As mentioned previously, stents with magnetic property could be removed using magnets. Ideal stent characteristics are easy insertion, completely

internal placement, resistance to migration, easy removing, radio-opacity, biologicalinertion, and chemical stability, resistance to encrustations, non-refluxing, excellent flow characteristics and reasonable price. Till date an ideal stent is yet to be developed. The most noticed problem is growth on the surface of stent. This could be 1) Tissue ingrowth 2) Growth of Micro organism 3)Combination of both. Modern day stent[32] would focus on these problems and would be designed to solve these problems. Recent interest in metallic stents has been sought with expectation. There are four general types of Metallic stents for ureteral use: 1) Self-expanding 2) Balloon-expandable 3) Covered 4) Thermoexpandable - stents. The most commonly used metallic stents in the ureter are the self-expanding stents. However urologists' interest has recently reoriented to covered stents, in an effort to minimise tissue ingrowth and resist microbial colonisation. Further developments in this line might see more refinement in stent technology. But till date no stent is ideal. This study focuses on certain issues which would be unaltered despite advancement in stent technology. This is based on the fact that any stent is a foreign body and the body response will be complex. Hence an analysis of these aspects which have little supportive data will enlighten more towards better patient outcome

PREVALENCE OF STENT RELATED COMPLICATION:

Stent related complications are more common. Hence numerous studies are available to document this phenomenon of stent related [18,22,30]complications by various authors. Let us consider the various published evidence on this topic as below.

Author	Frequency	Dysuria	Urgency	Suprapubic pain	Flank pain	Haematuria
Borboroglu et al	30/100	-	30/100	35/100	40/100	-
Byrne et al5	3.6/5	1.4/5	3.6/5	3.1/5	3.4/5	1.1/5
Chen et al6	25 Pts of 30 pts		25 Pts of 30 pts	2.3/10	2.3/10	-
Cheung et al7	-no data-	23 Pts of 29 pts	-no data-	2.7/10	19 Pts of 29 pts	16 Pts of 29 pts
Denstedt et al9	5.5/10	5.1/10	5.5/10	3.5/10	4.1/10	-
Damiano et al8	30 Pts of 50 pts	28 Pts of 52 pts	30 Pts of 50 pts	-	2.6/10	10 Pts of 52 pts
Srivastava et al12	16 pts of 26 pts	18 Pts of 26 pts	16 pts of 26 pts	2.23/10	12 Pts of 26 pts	-

Table above shows the results of multi-institutional meta-analysis. The study by various authors shows that majority of the patients report of irritative LUTS post stenting. Frequency and urgency are most commonly reported patient discomfort. Dysuria comes next in the order. Some patients report of suprapubic pain. Interestingly haematuria is not that common in all these studies. The prevalence of these symptoms (irrespective of the frequency of occurrence) is about a mean 50% when considered individually. The cumulated frequency is well over 80 - 90%. This result is consistent among other authors from all over the world in various reports. The single least occurrence reported[4] was 14% in 106 patients after DJ stenting by John et,al. Infact all these studies have not reported other morbidity related with stenting like pyrexia, urosepsis, work performance and psychological problems. It is however very clear from these studies that the spectrum of stent related LUTS is very varied in presentation.

The significance of stent related patient discomfort is less realized in routine urological practice. An analysis of stent related LUTS and its bothersome nature to the patient should be given due attention both in the outpatient and inpatient setting. An understanding of the problem and pathogenesis might guide to solve the problem better in critical situations. This is especially true in patients with stent related LUTS in situations like pregnancy and solitary kidney.

STENT RELATED SYMPTOMS AND QUALITY OF LIFE:

Innumerable symptoms occur[25] after DJ stenting. The symptoms vary from flank pain, lower abdominal pain, debris in urine, increased frequency of micturition, nocturia, urgency,incontinence, dysuria. Also there are other indirect and non-urological projections of these symptoms which include work performance, sexual matters, psychological distress and sense of general ill-health. In patient's words they describe themselves as "helpless", when they have stent related symptoms. Most of them have to restrict themselves from work due to pain. A number of studies have concluded that DJ stent related symptoms vary from 40% - 82%. RachidYakoubi et.al in their study found stent related bothersome symptoms in 80% of patients. The prevalence of the problem does not seem to very much with geographical location. Only minimal evidence is available on this regard. Nazaralimemon et.al of Pakistan found overall stent related complications in79.2%. In their study much data is available only on long term complications. They concluded that stent related complications are mostly due to mechanical properties of stent. But in contrast they recommended routine culture and sensitivity of urine in patients with stent related complication, as a concluding reark in their study. Thus it emphasizes again on the role of microbial culture in stent related symptoms, even though the problem may appear to be mechanical.

Chatterjee S et.al, analysed culture of urinary catheters and stent in their study. The study setting is in a tertiary hospital in India. They cultured 150 catheters and 31 DJ stents. Among them 130 catheters had microbial growth noted as significant. In their study all 31 DJ stents (100%) are positive for significant growth of bacteria. The study is very relevant because 1) Information is very well comparable to the setting of this study (a tertiary hospital in India). 2) Prevalence of positive stent culture is high (here it is 100%), and it is higher than that of catheters. This gives the clue that growth of microorganism on stent is an independent and a definite phenomenon which is often underestimated. The short coming of this study is that no correlation has been made with the clinical presentation of the patient. However the concluding remarks by the author are very valid.

1) Microbial growth on any urinary device is the rule rather than the exception, and

2) Such colonizations are mostly monobacterial with multiresistant organisms

The work by Joshi et.al is remarkable in the view of information on this problem in an entirely different perspective. H.B. Joshiet. Al[24] studied these bothersome parameters using validated questionnaire, with emphasis on Quality of Life(QOL). They concluded that Indwelling ureteral stents have a significant impact on Quality of life. In another study by the same author quantified the previous statement. The

author noticed reduced Health related quality of Life (HRQoL) in 80% of patients having DJ stents.

It is worth noticing that the psychological problem of patients with DJ stent is least evaluated and addressed in urology clinic. The classic study by Rocco Damianoet. al, demonstrates this aspect. The study was intended to study the Size of Ureteral Stent and its Impact in Urinary Symptoms and Quality of Life. In this study the author found no difference of symptoms and that of the size. But shockinglya high percentage of patients reported depression and anxiety associated with the stent. Hence the conclusions are 1) Stent size do not correlate with symptoms (hence the pathogenesis of stent related symptoms not necessarily confine to the physical characteristics of the stent. 2) Supports the previous statement that psychological impact[25] is more than actually thought about (the exact prevalence remains unknown). Perhaps the entire spectrum of symptomatology itself might be due to varied individual levels of tolerance and mental well being.

ShenPengfei et.al in their extensive meta-analysis showed that stent related symptoms affect significant percent of the population. In their study the morbidity was so significant it made them to issue a word of caution against unnecessary stenting.

INDICATORS THAT STENT RELATED SYMPTOMS ARE INDEPENDENT VARIABLES:

Stent insertion results in stent related symptoms. Though the insertion of stent seems to be causative for the outcome, analysis of available literature indicates otherwise. Stent related symptoms are independent of the stent itself. This also means, the symptoms are independent[16] of the design, material it is made up of, surface property and to some extent indication for stenting. The following literature review highlights these points

1)Modification of stent :

It has been hypothesized that the distal curl of the stent is the mian cause of stent related symptoms. In order to decrease ureteral stent-related bladder irritability, the 'tail stent'is designed toincorporate a tapered straight distal tail that resides in the bladder. Dual durometer stents incorporate a transition from a firm biomaterial at the renal end to a soft biomaterial or a fine loop at the bladder end, in an attempt to facilitate stent placement, reduce migration and minimize patient discomfort due to bladder irritation. In the most famous comparative study by Lingeman JE et al, the author found that there is no statistical difference in

symptom improvement noted. This ndirectly points out that stent related symptoms are not entirely due to stent design.

2) Adding pharmacological agents:

Then came the novel concept of Drug eluting Stents(DES). Antibiotic eluting stents were tried initially. Following the idea several other substances have already been used in DESs in an attempt to diminish stent-related adverse effects. Promising results have been demonstrated in the case of ureteral stents loaded with Triclosan and Ketorolac. Triclosan is[29] a broad-spectrum antimicrobial agent incorporated on ureteral stents to prevent stent infection. When Triclosan-eluting stents were indwelled for 3 months in eight patients a decreased antibiotic usage and significantly fewer symptomatic infections were noted. Nevertheless, a clinical benefit in terms of urine and stent cultures or overall subject symptoms was not revealed. Obviously these studies raise the following suspicion

1. There is no control over the release of drug and no way to ensure its working
2. The problem of drug resistence (antibiotic resistence) is not addressed
3. Most such stents have been tested only in vitro and results may not be comparable in vivo

3) Pharmaco-therapeutic manipulation:

Various pharmaco therapeutic agents were tried to circumvent the symptoms. They were the anti-cholinergics and α-blockers. The drugs tried were tolterodine,tamsulosin,alfuzosin etc. The trouble is that the primary problem is not addressed[13]. This is important especially in the patients who fail to respond to such agents. These patients were left with limited options which include removal the stent (irrespective of the consequence).

The following table summarizes these studies and their results.

Parameter studied	Author	Result / Conclusion of the study
Modification of the vesical end of stents [Stent with loops of loose plastic strings at the distal end – Percuflex "tail" stent]	Lingeman JE et al	No statistical difference in symptom improvement noted
Modification of the vesical end of stents [stent made with softer plastic on the lower end]	Davenport et al	Stents failed to reduce patient discomfort
Use of Drug (triclosan)-	Cadieux PAet al	Triclosan-eluting stent alone is not sufficient to reduce device-

eluting ureteral stents		associated infections and symptoms.
Use of α-blockers (Tamsulosin)	Rocco Damianoet al	Primary problem not addressed, non-responders have limited option
Use of tolterodine&alfuzosin	SeungChol Park et al	Primary problem not addressed, non-responders have limited option

All these studies indicate that a significant percentage of patients persist to have bothersome symptoms or suffer stent related complications in each of the group above. This again indicates that the problem is not related to mechanical properties of stent nor the problem could be circumvented by pharmacological manipulation.

TOOLS FOR SYMPTOM ASSESSMENT:

Lower urinary tract symptoms LUTS is a global term that includes storage symptoms, voiding symptoms as well as post micturition symptoms. The term LUTS[16] has clear definition and meaning. It comprises of group of defined symptoms which are non-sex specific and non-organ specific. IPSS is an important tool to assess LUTS

IPSS

IPSS was designed to be self-administered by the patient with speed and ease in mind. Hence it can be used in both urology clinics as well the clinics of primary care clinicians (General practitioners). In addition IPSS could be repeated multiple times with reproducible result. IPSS consists of seven questions and can be divided in to

1) Voiding symptoms
    a. Incomplete emptying
    b. Intermittency
    c. Weak stream
    d. Straining
2) Storage symptoms
    a. Frequency
    b. Urgency
    c. Nocturia

The characteristic additional feature of IPSS is that though it comprises of parameters related to these two groups of symptoms, it is not cause specific. It means that by applying the above questionnaire one cannot diagnose the cause.

Though it might appear as a short coming, it is in fact an advantage in other perspective. The IPSS score could be applied to measure the bothersome level of these symptoms in any pathologic condition that produces these symptoms. This could be as varied as from Urinary tract infection to BPH. As mentioned previously its lack of specificity to organ or sex makes still more versatile. The striking advantage is its ease in use.

The IPSS was originally based on the American Urological Association seven item symptom score (AUA-7). The 'Quality of Life' question was added by the World Health Organization when it was adopted by the International Consensus Committee as an international questionnaire for evaluating prostatic symptoms. Although the single 'quality of life' question may not capture the full impact of prostate symptoms, it can be used as a starting point for a doctor-patient discussion on management.

IPSS is well validated for assessment of LUTS after DJ stenting. This concept was proposed by H.B. Joshi et al in 2002 in their article. They prospectively studied the prevalence and bother of various urinary tract symptoms caused by indwelling ureteral stents using validated questionnaires, which was IPSS. The study consisted of 60 patients with unilateral ureteral stents. Of these, 30 patients were asked to complete the International Prostate Symptoms Score questionnaire,

with additional questions on dysuria, hematuria, and loin pain. The remaining 30 patients were asked to complete the International Continence Society questionnaire. The questionnaires were completed with a stent in situ and 6 weeks after its removal. Forty-eight patients (36 men and 12 women, mean age 52.8 years) completed the study. A large proportion (80%) of patients reported one or more urinary symptoms. Analysis of the IPSS data revealed impaired global quality of life owing to these urinary symptoms. The results of the International Continence Society study to a lesser extent were helpful. The author concluded that Patients with indwelling ureteral stents have a wide range of urinary symptoms that affect their quality of life. Validated questionnaire are useful in better understanding the urinary symptoms associated with stents and in providing patient counseling. The author also remarked that none of the existing questionnaires covered the entire range of symptoms,(it in turn made the same author to propose another questionnaire which we would discuss subsequently). It is because in their study they found a significant incidence of haematuria which is not present in the questionnaire, they made such final remark. But we could see in the multi-institutional study (discussed above) that haematuria is relatively less frequent among various authors. In summary by this study we could ascertain on the following facts.

1) Patients with indwelling DJ stents have wide range of symptoms
2) The prevalence of these symptoms affect significantly the quality of life of these patients
3) IPSS is well validated and could be used to analyse and document stent related bothersome symptoms.
4) IPSS is helpful in providing counseling for patients

Ureteral stent symptom questionnaire (USSQ)

It is a psychometrically[23] valid measure to evaluate symptoms and impact on quality of life of ureteral stents. It was used to evaluate stent related symptoms by Joshi et al. in their study published in 2002. USSQ was designed to cover most aspects of the problem and was claimed to be superior to IPSS in assessment of stent related symptoms. The final draft of USSQ addressed various domains of health affected by stents covering urinary symptoms, pain, general health, work performance, sexual matters and additional problems. It had 6 sections and 38 items. A total of 309 patients were asked to participate during different phases of the study. In phase 1 a structured literature search, 9 patient interviews and studies of 90 patients using existing instruments formed the foundation for the initial draft of our new questionnaire. In phase 2 the USSQ was pilot tested, reviewed by

experts and field tested in 40 patients to produce a final 38-item draft. In phase 3 formal validation studies were performed in 55 patients to assess validity, reliability and sensitivity to change. Discriminant validation was performed by administering the questionnaire to 3 groups of patients without stents. The validation studies showed the questionnaire to be internally consistent (Cronbach's $\alpha > 0.7$) with good test-retest reliability (Pearson's coefficient >0.84). The questionnaire demonstrated good construct validity and sensitivity to change shown by significant changes in the score with and after removal of stents.

Again the author in their concluding remark stated that Indwelling ureteral stents have a significant impact on health related quality of life.

Advantage of IPPS over USSQ

Now, we could observe that USSQ is very elaborate. The total number of items was 38. This is more than fourfold as that of IPSS. More over information on the test- retest reliability and application across wide section of population is yet to become available. As far as our society is concerned the population seeking treatment at government hospital has certain characteristics of its own. It is obvious (though not claimed for authenticity) that majority of the patients are economically burdened and have little education. They comprise the study group of this analysis.

It is impractical to expect these people to comprehend and complete the tedious USSQ. When in need for simplicity, IPSS is obviously superior.

MICROBIAL CULTURE AND BIO FILMS

Biofilms :

A biofilm is an accumulation of microorganisms and their extracellular products forming a structured community on a surface.

It is known that improvement of stent related morbidity is possible only by proper understanding of the various aspects of growth of pathogens on surface of biomaterials. Dirk Lange et al. in their study urged the need to understand this basic phenomenon first before proposing altered stent design including the latest Drug Eluting stents. In their view it is not possible or it is waste of time and resource to propose newer concepts for modern stents, if the pathogenic process is not completely understood. It in turn begins with the concept of microbial culture on these biomaterials which is the primary hypothesis for the study.

It is known that bacterial biofilms can colonise the surfaces of both tissues and implanted medical devices. The process of biofilm formation and the impact on the development and clinical course of infectious diseases, however, are still poorly understood. Effective preventive and therapeutic strategies still need to be

developed for device-associated infections. It is evident that with the steadily increasing number of biomaterial devices used in urology for urinary drainage like DJ stenting increases the incidence of device associated problems most in fact might be due to bacterial growth and biofilm formation.

The formation of biofilm generally consists of several main steps: the first step is the deposition of the microorganisms, next follows their attachment by microbial adhesion and anchorage to the surface by exopolymer production. After this process their growth, multiplication and dissemination can be observed. The initial event in this process is bacterial adhesion and the deposition of a host urinary component on the surface of the biomaterial leading to the formation of a conditioning film. The conditioning film does not cover the stent surface, but rather forms a “mesh-like” covering. The biofilm is usually built up of three layers. The linking or conditioning film is attached to the surface of a tissue or biomaterial, the biofilm base consisting of microorganisms and the surface film acts as an outer layer where micro-organisms can be released free-floating and spread to the surrounding compartments. The clinical importance is the failure of antimicrobials to penetrate these biofilms.

The prevalence of microbial growth and biofilm formation over DJ stents were not extensively studied. Information available in this regard is non-systematic, underpowered and not representative of general population.

S.Chatterji et.al studied the microbial culture of urinary catheters and indwelling ureteral stents in a random population within a hospital. 150 uro catheters and 31 ureteric stents were cultured. They made the following conclusions.

1) 89.33% of cases were positive for presence of biofilms.

2) Mono-bacterial Biofilms were exclusively seen on DJ stents

3) Bacteriuria demonstrated in the same patients though insignificant pointed towards biofilm.

The last conclusion means that demonstration of bacteriuria alone is not sufficient to confirm stent colonization and biofilm formation over indwelling DJ stent. In fact that bacteriuria is not mandatory in their study, indirectly points towards its poor reliability. The author made the final remark that bacterial colonization and biofilm formation was an inevitable phenomenon in case of DJ stenting.

Another study by Cormio Let,alanalysed the biofilm formation on various stent types in porcine model. 23 double-J stents of 8 different types were tested. They used scanning electron microscopy in their analysis. They found that there was no statistically significant difference in bacterial adherence to the various stent

materials.the final conclusion was microbial adhesion appeared to depend on the virulence of the bacteria rather than the properties of the biomaterials. This study has its limitation primarily because it was tested in porcine models. Still the conclusions were very illustrative of the problem of bacterial adhesion, virulence and biofilm formation on biomaterials.

Reid Get, al in their illustrative study sealed the remaining confusion with more certainity. Thirty ureteral stents were studied for microbial growth and biofilm formation. This study could be lauded for the fact that the author included urinary culture of these patients. They found pathogenic micro organism in 90% of the cultures. A definite biofilm was demonstrated in 55% of cases. The author also documented prescription and usage of antibiotic in all the patients (100%). This is a remarkable observation. The author made the following useful observations 1) Bacterial biofilms do occur on ureteral stents and urinary culture may not detect their presence 2) Unlike biofilm formation on many other prosthetic implants, colonization with Gram positive organisms on ureteral stents does not necessarily coincide with the development symptomatic infection.

So we could see from this study that microbial growth on DJ stent is unique and urinary culture may not detect it. The unreliability of urinary culture is demonstrated in other studies too. Though some studies show positive correlation

to urinary culture and stent culture (Joshi Ret,al in 2011), the inconsistency of these findings go well with the initial conclusion that urinary culture is not of substantial reliability. In addition we could also see that antibiotic prophylaxis has negligible effect on this phenomenon. The only limitation in this study is “How many patients were clinically symptomatic?”.Which we tend to address in this study of correlation of microbial culture to that of stent related LUTS.

Another study by GernotBonkat et al, also highlights the unreliability of urine culture done in conventional manner in predicting stent infection. The study was conducted comparing conventional urine culture to stent culture where the stent eas subjected to a process called sonication. The author definitely concludes that conventional culture may not detect infection on biomaterials like stents or catheter. The short comings of the study are when the culture is positive. In patients where culture is positive only after processing by sonication, the technology currently available is not standardized. In fact the process of sonication might even kill pathogens. But still the yield of microorganism by this process indicates a sterile urine doesnot exclude the presence of pathogens. Hence direct culture of the biomaterial (here it is DJ stent) is more reliable than conventional urine culture.

MATERIALS AND METHODS

1. Study group : Patients who were admitted in Kilpauk Medical College and Govt. Royapettah Hospital and undergone DJ stenting following which they developed significant lower urinary tract symptoms were included in the study.

2. Study design: Prospective clinical study

3. Materials:

Patient who had underwent DJ stenting with postoperative lower urinary tract symptoms were evaluated with a validated symptom specific questionnaire (International Prostate Symptom Score (I-PSS)). Patients with moderate to severe symptom score (8 and above) are studied. Stent was subjected to microbial culture at removal. Results analyzed

4. Study period – 1 year

Inclusion Criteria:

1. Patients who underwent DJ stenting (unilateral or bilateral) after intracorporeal lithotripsy for ureteric calculi.
2. Patients undergoing ureteric stenting for the first time
3. IPSS score 8 or above after DJ stenting
4. Age between 20 to 40 years

Exclusion criteria :

1. Histroy of severe lower urinary tract symptoms prior to DJ stenting
2. Gross haematuria
3. Associated bladder outlet obstruction
4. History of tuberculosis/Diabetes mellitus/medications for chronic ailment
5. Urine microbial culture positive at the time of DJ stenting
6. Cystoscopy revealing Urinary bladder abnormality
7. Residual stone in post operativeXray KUBU
8. Lower coil of DJ stent crossing the midline
9. Suspected stent migration
10. Benign Prostatic Enlargement

The study was approved by the institutional ethical committee.

In our study the complete clinical information is documented which includes age, sex, place of living, present and past clinical history, personal habits etc. Presence of co-morbid illness and use of any medications were sought for and recorded. The reason for DJ stenting and the operative records were obtained. Patients were individually assessed for their presenting symptoms. IPSS questionnaire was used and patient was offered help only if there was any

difficulty in comprehension of the question. The primal focus was on ensuring patient understanding of the question. No part of the question was modified. The results recorded. Patient underwent routine urological and basic biochemical investigations. A urine culture and sensitivity was done. A plain xray KUBU and USG examination were done in all these patients to look for any significant residual calculi. All these patients were subjected to stent removal observing maximum sterile precautions. The procedure was noted and any difficulty in removal of stent was recorded. The stent was received in a sterile culture tube and the distal end (vesical end) was cut with sterile scissors and sent for culture. The stent was processed in the microbiology department. It was initially cultured in Brain Heart Infusion broth (BHI) as soon as it is received in the department. Then isolates are cultured in McConkeyagar and Blood agar. Sensitivity for antibiotics was done subsequently.

OBSERVATION AND RESULTS

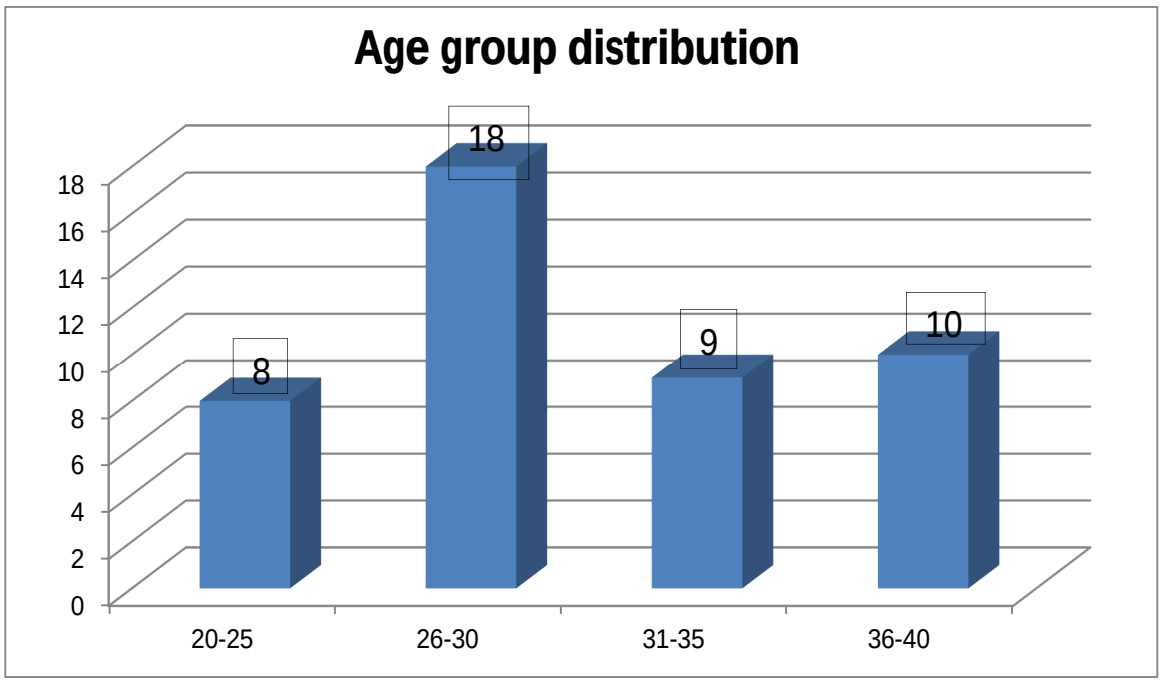
In our study the mean age of the patients is 30.711 years. The age limit of the study population is between 20 -40 years. When correlated to age groups, the dominant group was between 26-30 years. 28 were male patients and 17 were female patients. 16 had stent on right side, 25 had stent on left side and4 had bilateral stents.

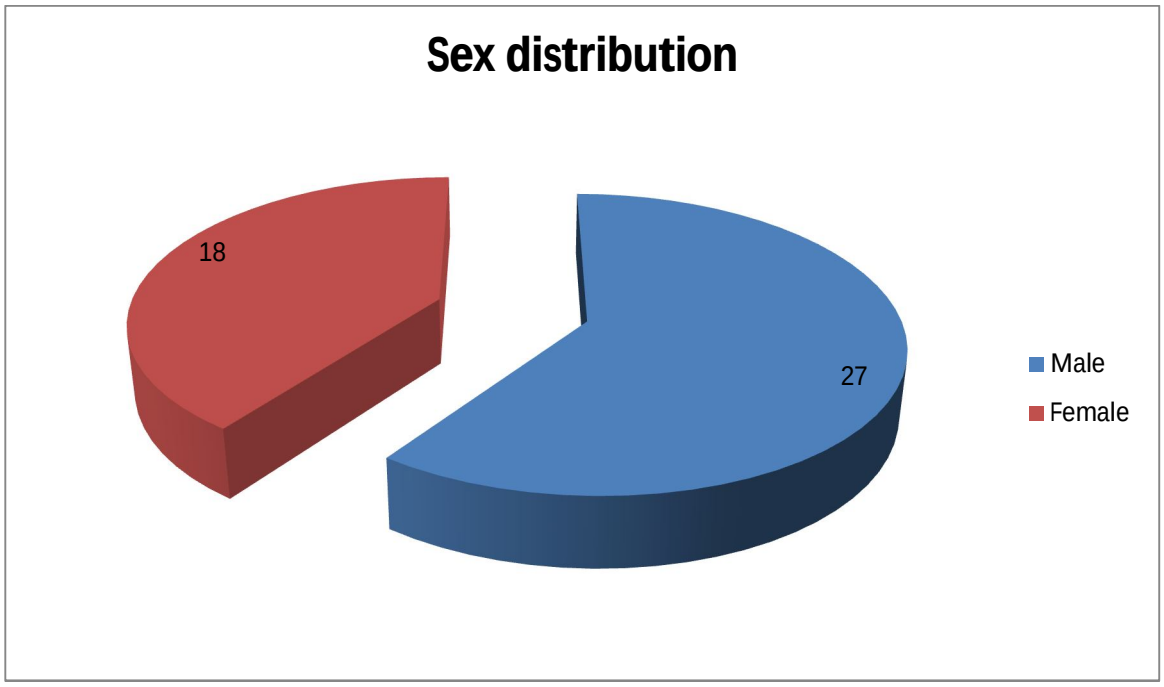
Sample size	45
Mean age	30.711
Male	28
Female	17
Right side stent	16
Left side stent	25
Bilateral stents	4
IPSS(mean)	20.25

STATISTICAL ANALYSIS

Data were analyzed using the statistical analysis package SPSS version 20 for Windows and Medcal software. Three analyses were undertaken: 1)univariate analyses of the association of each variable with Stent culture 2) multivariable logistic regression to predict outcome of DJ stent related symptoms.3)) multivariable logistic regression to predict outcome of DJ stent related symptoms and microbial culture of DJ stent (with or without culture of urine). In the univariate analysis, Chi-square test and Fisher's Exact Test was used for categorical variables and Student's t-test or Mann-Whitney test was used for continuous variables. All testing was two-sided. Univariate relative risk ratios and multivariable analyses were done by assigning the continuous variables into discrete variables, based on their being above or below a set value. The Multivariable logistic analysis was done in a stepwise manner. One variable was entered at a time into the classification equation. The variables were tested individually one at a time and the results looked for. If significant it is tested in combination with additional variable and the statistically appropriate test done. Finally association between multiple variable was assessed.

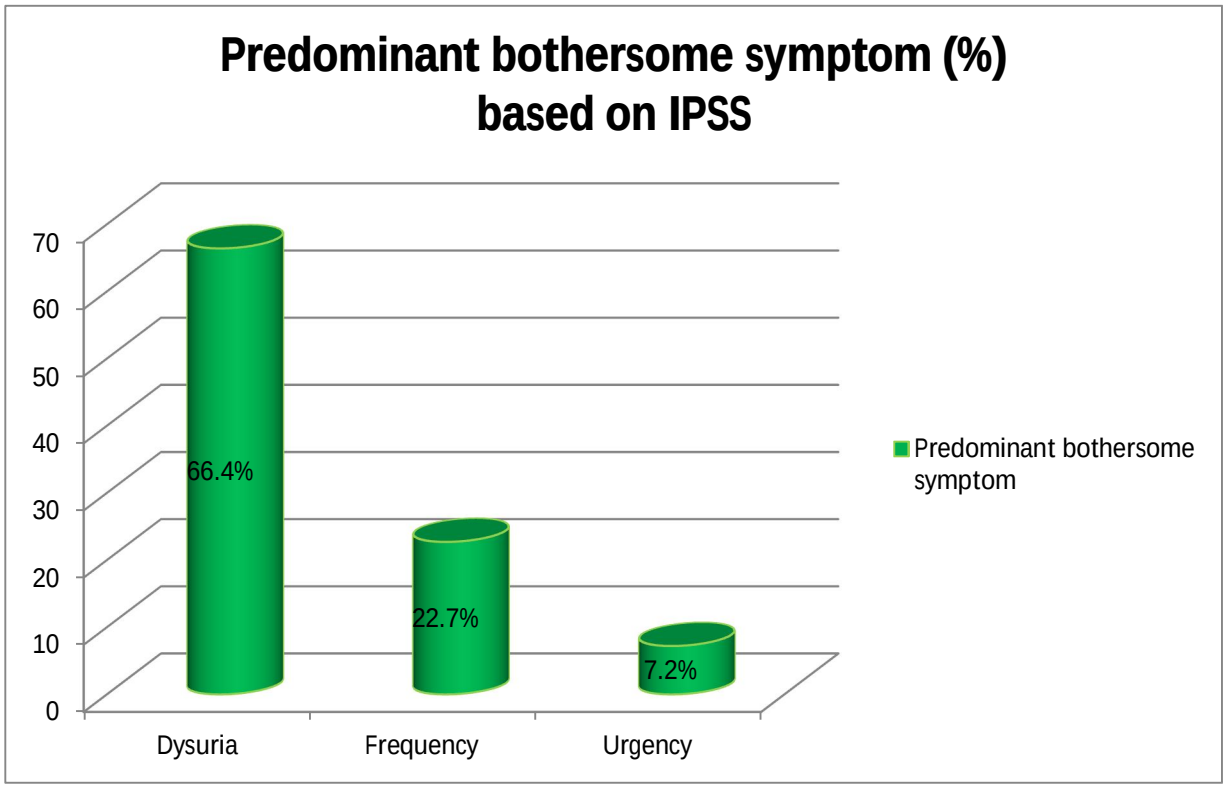
Study group characteristics

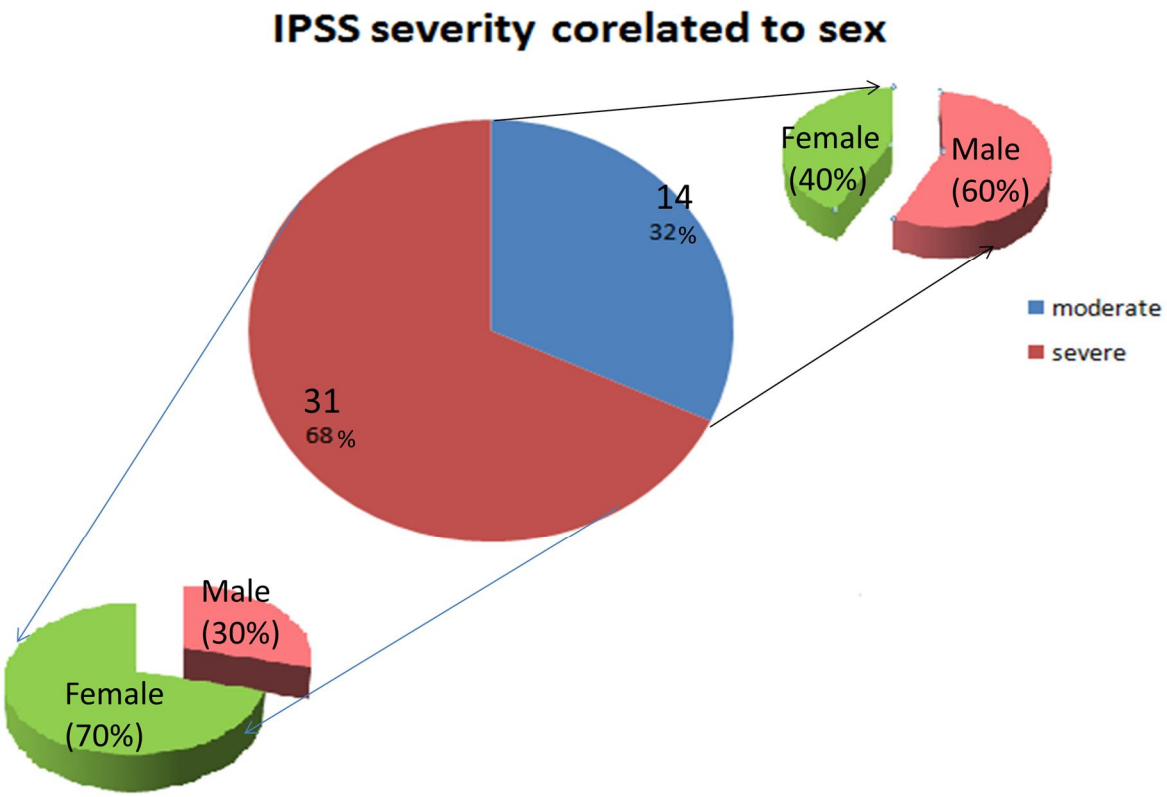




IPSS:

The mean IPSS was 20.25. The most common bothersome symptom (using IPSS) was dysuria(66.4%) followed by frequency(22.7%) and urgency (7.2%). 31 (68%)patients had IPSS corresponding to ‘severe’ category(IPSS 20-35). 14 (32%) patients had IPSS corresponding to ‘moderate’ category(IPSS 8-19).

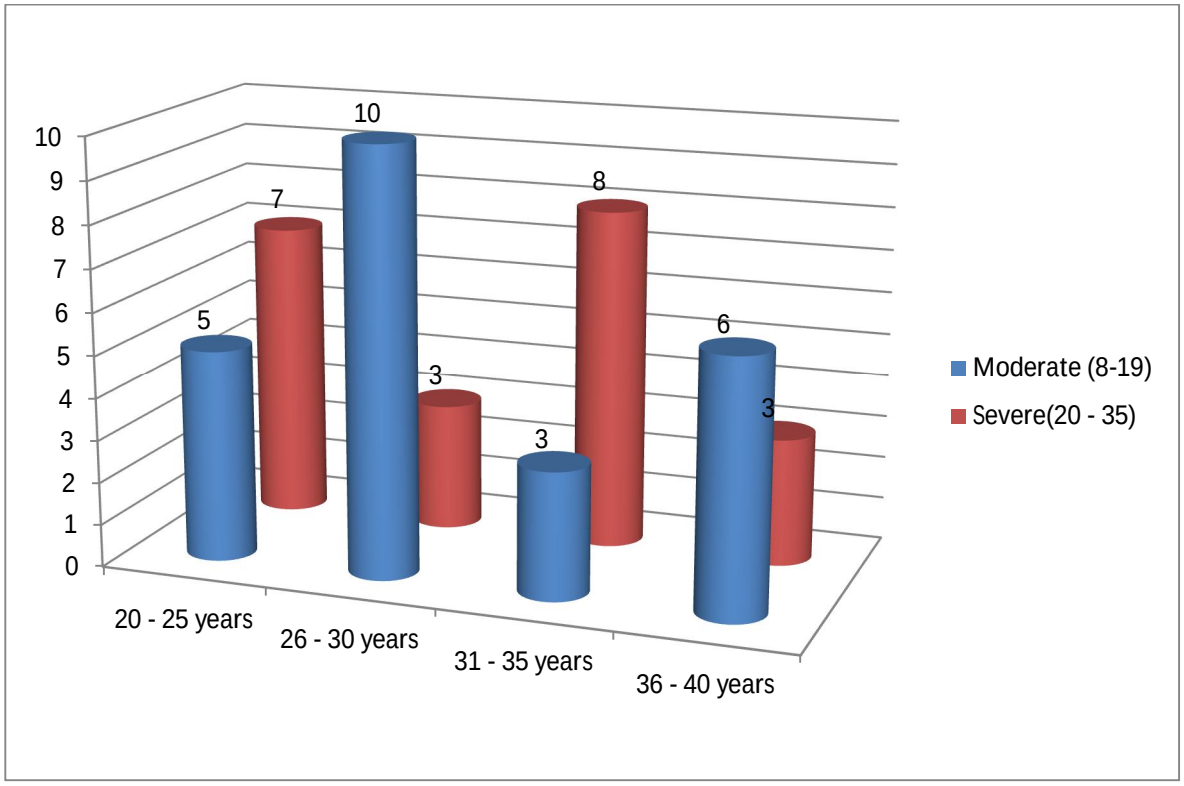




The symptom wassubclassified and plotted for sex distribution. When analysed for correlation with sex severe females reported more of severe IPSS 70%.

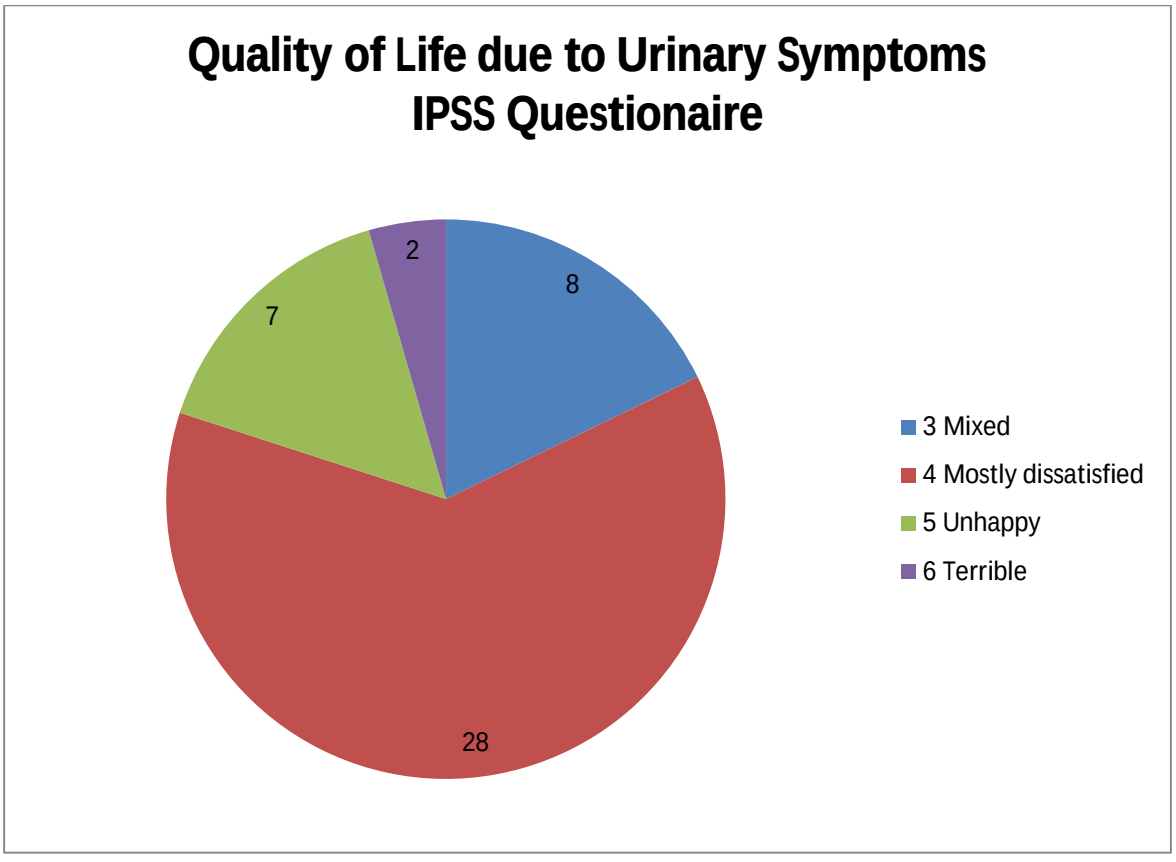
IPSS was also correlated to the age group. The moderate symptoms (IPSS 8-19) predominated in the age group 26-30 years. IPSS severe symptoms (20-35) existed in the age group 31-35 years

IPSS severity(mean)correlated to age groups



IPSS Quality of Life:

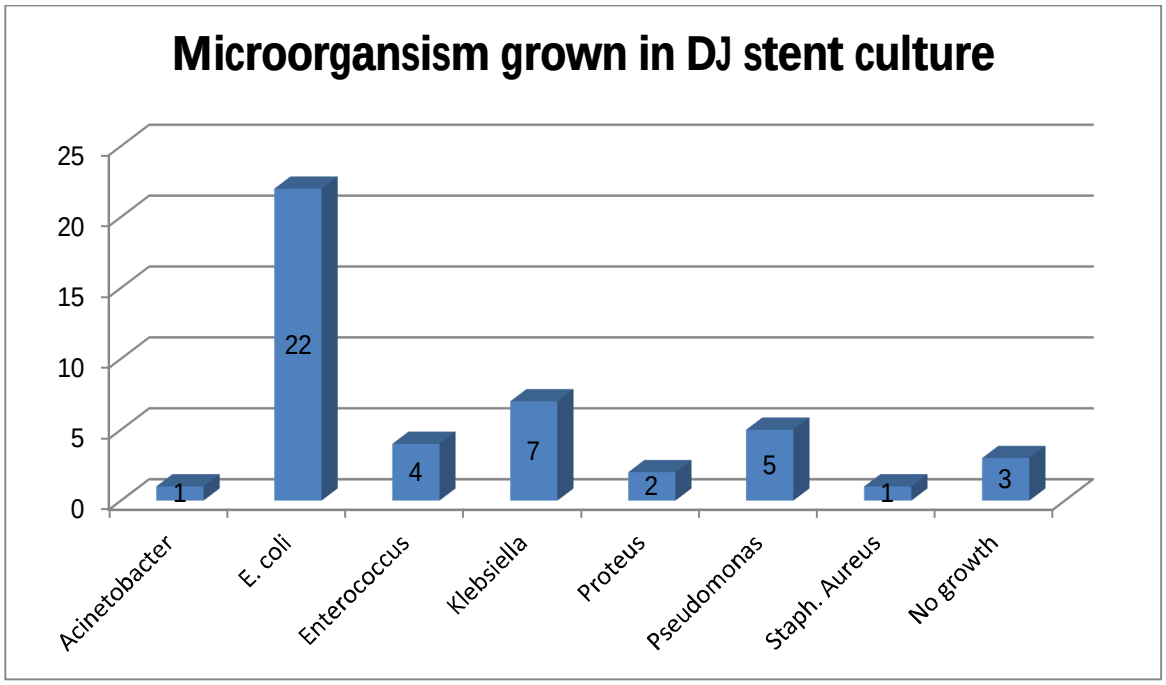
All patients responded with the minimum score of 3(mixed feel regarding spending the rest of life with existing symptoms).28 patients (62.22%) had given a score of '4' corresponding to 'mostly dissatisfied'. 7 patients (15.55%) had reported IPSS QoL 5 corresponding to 'Unhappy'. 8 patients (17.77%) reported IPSS QoL 6 corresponding to 'terrible', if they were to continue with existing symptoms.



Microbial culture:

Microbial culture of urine was done as a part of routine urological workup. Upon removal of DJ stent it was cultured as described previously. 46specimens had growth of microorganism positive on the DJ stent (93.87%).When corrected for bilaterality the percentage was 93.33%. 20patients had positive urine culture (44.44%). All four patients with bilateral stents had the same organism grown in culture. The most common organism grown was E.coli in both DJ stent (48.8%) and urine culture (28.8%). The second most common organism was Klebsiella, followed by pseudomonas. Other organisms were Enterococcus, Proteus, Acinetobactor and Staph. aureus. The positive cultures were predominantly unimicrobial.

Organism	**DJ stent culture (Adjusted to bilaterality)**	**Urine culture**
E. coli	22	13
Klebsiella	7	3
Acinetobactor	1	
Proteus	2	1
Pseudomonas	5	2
Enterococcus	4	1
Staph. aureus	1	
No growth	3	25


Microorgansism grown in DJ stent culture
25
20
15
10
5
0
1
22
4
7
2
5
1
3
Acinetobacter
E. coli
Enterococcus
Klebsiella
Proteus
Pseudomonas
Staph. Aureus
No growth

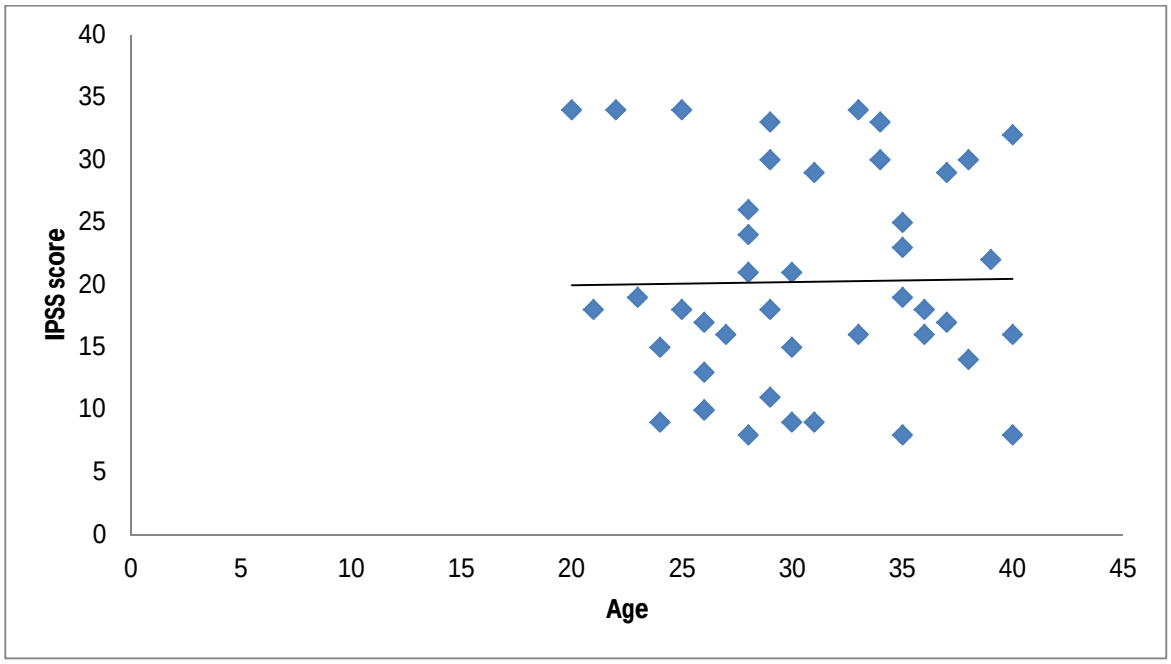
Age Vs IPSS:

The age group were analysed for association with severity of symptoms scaled with IPSS. The IPSS score was categorized according to moderate (IPSS 8-19) or sever (IPSS 20-35). It was correlated with the age group. Chi square test was applied and result tabulated. The dominant age group (26-30 years) was tested for significance. Results showed no significant association (P value 0.68).

Age group	Severity score		Chi square	P value
	Moderate	Severe		
20 – 25	5	4		
26 – 30	10	6	1.51	0.68
31 – 35	4	6		
36 – 40	6	4		

The analysis extended to the total population and plotted in distribution graph.

Result showed no significant association (p=0.913).



r = 0.017, p = 0.913

Gender Vs IPSS:

Relation of sex and severity of IPSS was tested. The major group, which comprised the male population was analysed for association with severity of IPSS. Analysis made with Chi square test and result tabulated. Result showed no statistical significance (P value = 0.168).

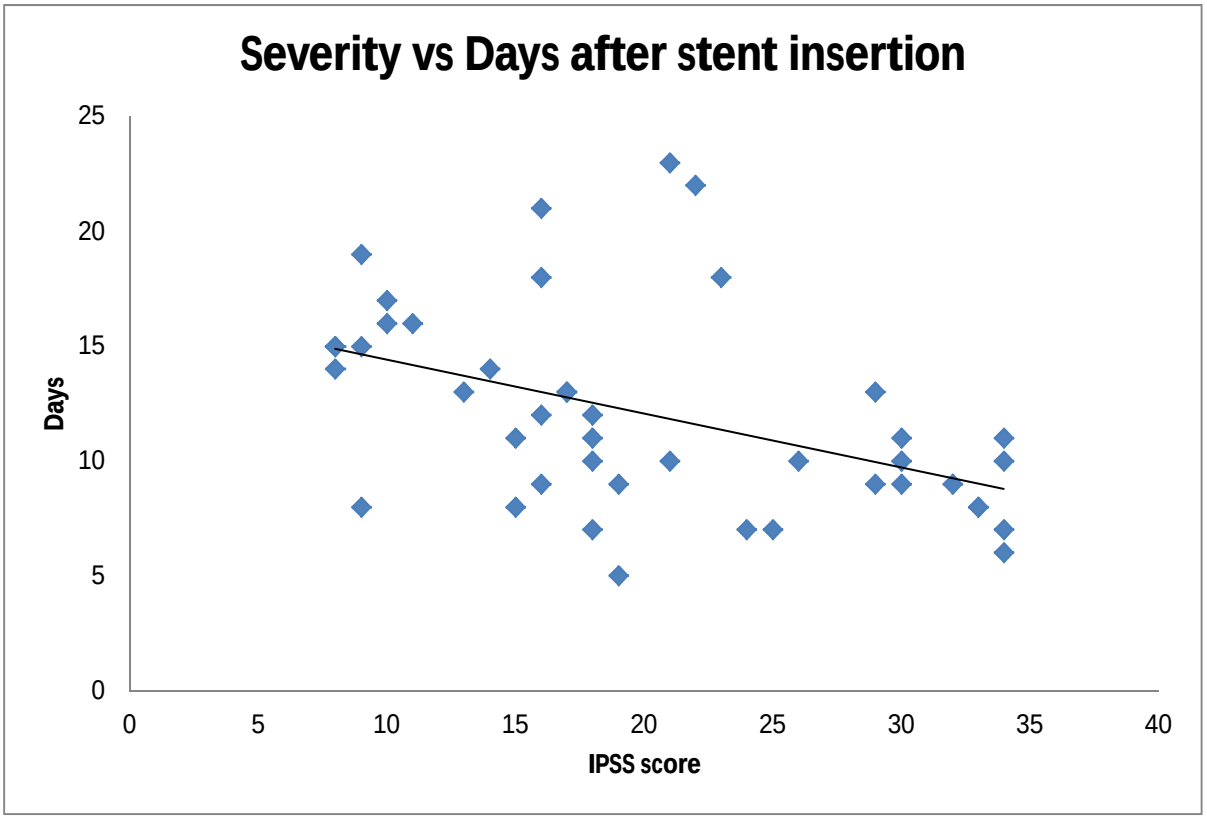
Gender	Severity score		Chi square	P value
	Moderate	Severe		
Male	19	9	1.90	0.168
Female	7	10		

IPSS severity VS early stent removal:

This was tested in two parts. The variables were IPSS score (either moderate or severe) and postoperative day of stent removal. Fisher exact test was applied

In the moderate IPSS group (IPSS 8-19), when tested for relevance using Fisher exact, there was no significant association (Fisher 0.72 Pvalue 0.396)

In the severe group (IPSS 20-35) after regression analysis showed statistically significant association (Pvalue 0.002)



r = -0.454, p = 0.002

IPSS severity and Positive microbial culture:

IPSS severity was analysed for linkage with positive microbial culture. This was done in four settings. First the analysis for done to test IPSS score to that of positive microbial of DJ stents. Then the test repeated for positive microbial culture of urine. In the third time it was tested for combined positive urine and stent culture. Finally the relevance for IPSS group moderate(IPSS 8-19) and severe(IPSS 20-35) was analysed.

The relationship between stent culture and IPSS score was tested. And the result was no statistically significant association (P value 0.26).

The relationship between urine culture and IPSS score was tested. The result was not statistically significant (Pvalue 0.27).

The analysis was done for combined (DJ stent and urine) positive microbial culture. IPSS score correlated to severity of combined microbial culture. The result was statistically significant with P value 0.001

IPSS severity and combined positive microbial culture

Severity	Combined positive culture		Chi square	P value
	Yes	No	10.37	0.001
Moderate	4	21		
Severe	13	7		

Predictive value of urine culture for positive Stent culture:

The results of urine culture were correlated with the results of stent culture. The result was sought for the sensitivity, specificity, positive predictive value and accuracy. The results were tabulated as below.

Predictive value of urine culture:

Urine culture	Stent culture		Total
	Positive	Negative	
Positive	20	0	17
Negative	22	3	28
Total	42	3	45

Sensitivity – 42.1%

Specificity – 100%

Positive predictive value – 100%

Negative predictive value – 21.4%

% of false negatives – 57.9%

% of false positives – 0%

Accuracy – 48.3%

Positive microbial culture and early stent removal:

The significance of positive microbial culture (of DJ stent, urine and combination of both) and the predictability of early stent removal was analysed. Timing of standard stent removal (3 weeks) was initially tested. Then the patient group was divided arbitrarily in to two. One group with stent removal early than 10 days and other after 10 days. The results were analysed.

In the first group, the timing of standard stent removal at 3 weeks was tested with population having positive combined microbial culture, was tested for statistical significance, there was no statistical significance (P value 0.247).

When the test was applied to the arbitrary division of groups based on 10 days as early and beyond 10 days as late, the result was found to be statistically significant(P value = 0.003).

Combined positive microbial culture Vs early stent removal(standard timing):

Combined positivity	Stent removal		Fisher	P value
	Early	Late	1.84	0.247
Yes	16	1		
No	25	3		

Combined positivite microbial culture and early stent removal (with redefined variable):

Combined positivity	Stent removal		Chi square	P value
	≤ 10 days	>10 days		
Yes	13	4	8.85	0.003
No	8	20		

DISCUSSION

Insertion of ureteral stent is a common procedure in modern urology. It is a simple and effective method to ensure obstruction free flow of urine from the renal pelvis to the bladder. Ureteral stents are commonly used while management of stone disease. Ureteroscopy is a common procedure done for ureteric calculus causing obstruction. Intracorporeal lithotripsy is done to fragment the stone during such procedure. This procedure is usually followed by the insertion of DJ stent. In our hospital we experience patients coming for followup with lower urinary tract symptoms appearing for the first time after undergoing aforementioned procedure. Evaluation of these patients revealed absence of any calculi and most of them can be attributed to the DJ stent itself. This is an established and well documented observation in various publications. It is also true that the exact cause and mechanism for this stent related lower urinary tract symptoms are still unknown. Furthermore the correlation of DJ stent culture to that of these stent related symptoms are the least evaluated.

We accrued 45 patients based on our selection criteria. The age limit was from 20 – 40 years. This was to eliminate the possible sampling error that occurs in old age where LUTS is more common. Patients are restricted to the age group to minimize the possibility of bias that could arise in higher age. Established facts

indicate both IPSS and incidence of infection are influenced by age, the most skewed at the extremes. Hence we excluded paediatric population and upper age limit in this study is 40 years. Though the primary aim is to identify microorganism on DJ stent and not to identify urinary tract infection, the restriction of age group soundly ensures exclusion of unnecessary bias. It has also been ensured that the standard deviation is well within the confines necessary for drawing meaningful conclusions. In our study the standard deviation of age is 5.47 years.

The patient in this study group is a mixed group containing both outpatients and inpatients. The patients in the study group are treated initially as follows for their symptoms. Following DJ stenting we have standardly prescribed Paracetamol tablets and flouroquinolone (mostly Ciprofloxacin) for 3 days. Those patients who have persistent symptoms were subjected to urine routine analysis and culture sensitivity and treated accordingly. None of the patients in this study group were prescribed any α blockers or anticholinergics by us. This we have not prescribed primarily because 1) There is still no consistent evidence testifying the effectiveness of these agents. 2) The hypothesis proposed for this study suspects infection as a cause of LUTS after DJ stenting. Hence it is irrelevant if any drug other than antibiotics (based on appropriate supportive evidence in the form of culture&sensitivity) should be prescribed. This contradicts the purpose of the study. Also if infection is suspected any drug that will hinder bladder emptying

(like anti-cholinergics) and prolonging urine stasis is dangerous and unethical (based on the proposed hypothesis). However whether some patients in our study group has undergone treatment with various available pharmacological agents either by by themselves or upon prescription by someone else (other than those involved in the study) could not be completely ruled out. The medication that they could have have taken is so diverse that complete documentation and analysis is technically not possible. This could be due to concealment of facts. Could be in part due to poor documentation of medicines taken by these patients. Even if it is narrowed down to one single agent, the diversity of available brands complicates the issue further. One thing was very certain.None of them reported increase in symptom 'out of proportion'. In this minor group of patients, they had no benefit by taking these drugs. This is evident by the very fact that they have come to the hospital for the symptoms. This again strongly supports our hypothesis that the real cause is definitely unknown and is not amenable to these pharmaco-therapeutic agents (either α blockers or anti-cholinergics etc.) and most importantly, infection as a potential cause cannot be ruled out. To definitely establish an association with these pharmaco-therapeutic agents will require a randomized control trial with much larger population. Investigating along these lines is beyond the scope of this study. The concern that this population might skew the results is unwarranted. This is because; the accrual of the study group is

by random selection. Hence there is every chance that this group too is evenly distributed in the population proportion of this study. In such case they will not statistically influence the results. In fact, the very existence of this minor group of patients adds strength to the study by being a representation of the general population. This allows us to extrapolate the results with high degree of confidence.

IPSS is a validated questionnaire for LUTS assessment. We utilised IPSS in all our patients and their response was documented. IPSS has 7 items and one separate for Quality of Life. IPSS has a possible score between 0-35. Among them patients with score from 0-7 are taken to have mild symptoms. Patients with score 9-18 are taken to have moderate symptoms. Score from 20-35 are considered severe. In our study the mean IPSS score was 20.25. This value is categorized under severe symptoms, indicating that most of the patients are suffering significantly due to stent related symptoms. An analysis of this further revealed that female patients tend to have more severe stent related symptoms. Symptom severity tends to occur in certain group, with moderate symptoms more common in 26-30 years and severe symptoms more common in 31-35 years. This appears as though supporting the previous theory that Lower urinary tract symptoms are sever as the age increases. We did a test for statistical significance and found the Pvalue

0.913 (not significant). Hence in our study IPSS was not influenced by age probably due to our restricted inclusion criteria.

In our analysis we found that female patients tend to have more severe LUTS. We could propose explanation for this based on social stratification, psychological health and other factors. But from our analysis the cause for this prevalence among female population is unknown. One other possibility is by correlating incidence of infection in this population subgroup. It is well known that females have higher incidence of UTI than males. This study in fact has the same purpose i.e, to identify infective cause for DJ stent related symptoms. If the previous statement is true then by mathematical association, we could suspect the reason for higher incidence of severe LUTS in female patients who had undergone DJ stenting might be due to infective microbial agents. However, in our study the test for statistical significance of positive DJ stent culture to that of severity of IPSS in this female population was not significant. This could in part due to relatively small female sample size in our study group.

IPSS has in addition the ability to assess Quality of Life of patients with stent related LUTS. In our study all our patients reported a minimum of 3 (indicates mixed feeling to continue living with current LUTS). The majority of the patients gave score of 4=unhappy. This could because, the very reason patient has come to the hospital is he has bothersome symptoms related to DJ stenting.

Statistical testing however revealed lack of its influence on other variables and absence of any obvious bias.

In our study up to 93.33% patient had positive microbial culture on DJ stent. It is higher that currently available published reports. Here again the reason could be the inclusion criteria. We excluded IPSS of mild symptoms (IPSS 0-7). Infact this result indirectly suggests positive correlation of DJ stent culture to that of bothersome LUTS. Though a subsequent statistical analysis was required to confirm this claim. The most common organism grown in our study was E.coli in both DJ stent (48.8%) and urine culture (28.8%). This result is comparable with most other published report. This in turn points out indirectly of a positive microbial culture to be associated with stent related LUTS. Proving this statistically is very difficult and may require much larger sample size.

Analysing the effect of IPSS on stent removal, we are able to observe positive linkage of early stent removal to severe IPSS. In the severe group (IPSS 20-35) after regression analysis showed statistically significant association (Pvalue 0.002). This is a favorable observation to prove our ‘research hypothesis’ and against the ‘null hypothesis’. This could be substantiated if we could demonstrate positive linkage of IPSS to stent culture. Since 90% of our patient had positive microbial culture, we could conclude that the linkage is significantly strong. But still for statistical purpose we slightly modified it as ‘Combined positive microbial

culture’ which include positive DJ stent as well as positive urine culture. This was significantly associated with severe IPSS and early stent removal. The test was statistically significant (P value 0.001).

The predictive value of urine culture to identify coexisted positive microbial culture of DJ stent was tested. It is well known that urine culture is not so reliable. In our study we found support for this proposition. The urine culture had Sensitivity of 42.1% and Specificity of 100% for identifying coexisted DJ stent growth. It had a Positive predictive value of 100% and Negative predictive value of 21.4%. Hence its accuracy is estimated to be 48.3%. This result is comparable with that of other authors.

Finally we tested for relation between stent culture and early stent removal. There was a positive relationship between DJ stent culture and earl stent removal (<10 days). This is more so if the patient had concurrent positive urine culture.

CONCLUSION

- The prevalence of stent related symptom is significant in incidence.
- If the stent related symptom occurs, then mostly it is of the severe category of IPSS (score20-35).
- Based on the study it was found that IPSS severity was predominant in female population but was not statistically significant.
- IPSS severity and prevalence of stent culture are not influenced by the side of stent or bilaterality.
- Age of the patients doesnot predict IPSS severity. With reference to age the dominant group between 20 to 40 years belonged to the subgroup 31-35 years. This prevalence also was not statistically significant predictor of increased IPSS or early stent removal.
- When assessed with Quality of life questionnaire based on IPSS the predominant group of patient reported that stent related symptoms a score of 4 (mostly dissatisfied).
- E.coli was the common micro organism grown followed by Klebsiella and Pseudomonas. This pattern was the same for both DJ stent culture and Urine culture.

- The culture characteristics revealed a predominant unimicrobial growth pattern.
- Stent removal was early in patients who had positive culture of both DJ stent and urine combined. There is also a strong linkage of higher IPSS score to that of positive DJ stent culture and positive urine culture.
- IPSS score is a significant predictor of positive stent culture.
- IPSS score severity is a definite predictor of early stent removal (before 10 days).
- IPSS severity is a predictor of positive microbial stent culture and urine culture. IPSS severity is also conversely predictable by combined microbial culture positivity.
- Multivariate analysis reveals that the severe the IPSS, the higher chance of positive microbial culture (either DJ stent, urine or both), the earlier the stent removal in these patients.
- Urine culture has high positive predictive value for presence of DJ stent culture. However its accuracy from this study is only 48.3%.

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